

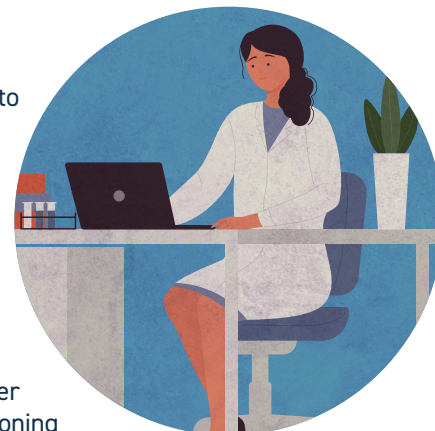
# Tecovirimat IND Registry for Providers and Facilities



## Why register?

An online registry is now available for providers and affiliated medical facilities providing tecovirimat under the CDC-held expanded access Investigational New Drug (IND) protocol to register. All new providers must register with the tecovirimat IND Online Registry.

- The tecovirimat IND Online Registry enables compliance with IND regulations.
- Providers must be registered to access electronic tecovirimat IND forms for convenient, time-efficient, and secure completion and submission to CDC. Forms include:
  - Form FDA 1572 (Statement of Investigator) (Required)
  - Patient Intake Form (Required)
  - Clinical Outcome Form (Optional)
- The online registry provides an up-to-date list of participating providers and facilities under the tecovirimat IND protocol. This will help state and health departments guide pre-positioning and distribution of tecovirimat, inform treatment access, and identify distribution and treatment gaps.



**Note:** Providers who submitted tecovirimat IND forms with a valid email to CDC prior to the online registry are grandfathered in as registered providers and should receive a verification email automatically.

## Steps to Register and Access Electronic Patient Intake and Clinical Outcome Forms

### Register Online

- Register via “registry link” as participating providers and facilities to be covered under the CDC-held tecovirimat IND protocol.
- The electronic Form FDA 1572 can be completed through the online registry if it was not previously submitted to CDC.



### Complete Verification

- Upon registration, the provider will receive the first email from “CDC IMS tecovirimatIND” <noreply@dcipher.cdc.gov> confirming registry as a participating provider to prescribe, dispense, and/or administer tecovirimat under the CDC-held IND.
- Please complete the brief verification steps included in the email to access the electronic Patient Intake and Clinical Outcome Forms.



### Grandfathered Providers

- A provider who has submitted tecovirimat IND forms to CDC with a valid email address prior to online registry activation (“grandfathered providers”) will automatically receive the verification email described in step 2.
- Any provider who does not receive this email must register through the [Tecovirimat IND Online Registry](#).

### Access Patient Intake Form (Required)

- Upon verification, a provider will receive a second email with a secure link to electronically fill out the Patient Intake Form.
- The secure link can be accessed multiple times to complete the form for each patient treated.
- For each patient treated with tecovirimat, providers must submit the completed form to CDC within 7 days of therapy initiation.
- **Note:** For security reasons, the form must be completed and submitted in one sitting.



### Access Clinical Outcome Form (Optional)

- Upon verification, a provider will receive a third email with a secure link to electronically fill out the Clinical Outcome Form.
- The secure link can be accessed multiple times to complete the form for each patient treated.
- For each patient treated with tecovirimat, providers are requested to submit the form to CDC within 7 days of the last patient follow up.
- **Note:** For security reasons, the form must be completed and submitted in one sitting.



For any questions regarding the tecovirimat IND Online Registry and/or electronic forms, please email [CDC IMS tecovirimatIND](mailto:CDC IMS tecovirimatIND).